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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/597,179 | 06/20/2000 | Maura Rooney | BSP2102US02 | 5883 |

21323 7590 12/31/2002

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EXAMINER

WINGOOD, PAMELA LYNN

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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3736

DATE MAILED: 12/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/597,179

Applicant(s)
Rooney

Examiner
Pamela Wingood

Art Unit
3736



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10.09.02
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-26, 28-30, and 32-40 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-24, 26, 28-30, and 32-40 is/are rejected.
- 7) ☒ Claim(s) 25 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 22-24, 26, 28, 30, 32, 34-35, 38, are rejected under 35 U.S.C. 103(a) as being unpatentable over Morrison (986) in view of McMahon (485) and Slaikeu et al.

Morrison (986) discloses a guidewire having an elongate tapered core of stainless steel or other materials, having a length of coil (13, Col. 2, Ins. 64-67) of stainless that covers a substantial portion of the core and a Tungsten element in the distal portion and a Teflon (TM) coating to provide lubricity (Col. 3, Ins. 5-10) ; however, it does not have a distal tip of a polymeric material or a core of Nitinol.

McMahon (485) discloses a guidewire having a polymeric tip in an analogous art for the purpose of preventing patient trauma (Col 3, Ins. 59-60, 20) and Slaikeu et al. discloses a core of nitinol in an analogous art for the purpose ensuring distal flexibility. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the device of Morrison (986) as shown by McMahon (485) and Slaikeu et al. because the use of the atraumatic polymeric tip together with a floppy guidewire would minimize the likelihood of patient trauma during insertion.

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3. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Morrison (986) in view of McMahon (485) and Slaikeu et al. as applied to claims 22-24, 26, 28, 30, 32, 34-35,38 above, and further in view of Beisel.

Morrison (986) and McMahon (485) and Slaikeu et al. disclose the limitations above but do not disclose the use of a precipitation hardenable alloy for the second material.

Beisel discloses a precipitation hardenable material for the second material in an analogous art for the purpose of aiding in guidewire insertion. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the device of Morrison(986), McMahon (485) and Slaikeu et al. as shown by Beisel because the hardened alloy would increase coil stiffness and enhance torquability. (Col. 12).

4. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Morrison (986) and McMahon (485) and Slaikeu et al. as applied to claims 22-24, 26, 28, 30, 32, 34-35,38 above, and further in view of Gambale.

Morrison (986) and McMahon (485) and Slaikeu et al. Disclose the limitations above but do not disclose a guidewire having coils of varied pitch.

Gambale discloses a guidewire having coils of varied pitch in an analogous art for the purpose of varying flexibility.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the device of Morrison (986) and McMahon (485) and Slaikeu et al. as

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shown by Gambale because the varied pitch would provide some flexibility in the proximal stiffer region.

5. Claims 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Morrison (986)

and McMahon (48) and Slaikou et al. as applied to claims 22-24, 26, 28, 30, 32, 34-35 and 38

above, and further in view of Whitborne (517).

Morrison (986) and McMahon (48) and Slaikou et al. disclose the limitations above but do not disclose the use of a colored coating.

Whitborne (517) discloses the use of a colored coating for medical devices in an analogous art for the purpose of to enhance the performance of the device. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the device of Morrison (986) and McMahon (485) and Slaikou et al. as shown by Whitborne (517) because the colored coating would assist in identification.

6. Claims 37, 39, 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morrison and McMahon and Slaikou et al. as applied to claims 22-24, 26, 28, 30, 32, 34-35, 38 above, and further in view of Hodgson.

Morrison and McMahon and Slaikou et al. disclose the limitations above but do not disclose the use of multifilar coils or coils of a rectangular cross section.

Hodgson discloses a guidewire using coils of rectangular multifilar construction in an analogous art for the purpose of transmitting torque. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the device of

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Morrison and McMahon and Slaikeu et al. as shown by Hodgson because such a construction enhances torque transmission. (Abst.)

Allowable Subject Matter

7. Claim 25 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

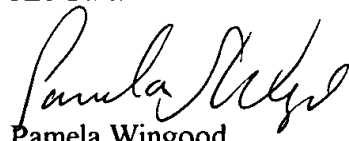
Response to Arguments

8. Applicant's arguments with respect to claims 22-54 have been considered but are moot in view of the new ground(s) of rejection.

Applicant appreciates the new arguments in the latest response. However, the Morrison reference is still being used to reject many of the claims. Furthermore, the Examiner has applied a new reference Slaikeu et al, to teach the Nitinol core of the guidewire. The Applicant's arguments regarding the McMahon reference are unclear because the reference expressly discloses a soft rounded distal tip. Clarification is required.

Any questions relating to this application can be addressed to Pamela Wingood who can be reached on (703)308-2676.


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Pamela Wingood

Patent Examiner

December, 29 2002


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